

DEVELOPMENTAL PLANNING GRANTS FOR MUSCULAR DYSTROPHY RESEARCH  
CENTERS

RELEASE DATE: October 31, 2002

RFA: AR-03-002

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov/>)

National Institute of Child Health and Human Development (NICHD)

(<http://www.nichd.nih.gov/>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov/>)

LETTER OF INTENT RECEIPT DATE: January 15, 2003

APPLICATION RECEIPT DATE: February 24, 2003

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PURPOSE OF THIS RFA

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Child Health and Human Development (NICHD) seek developmental planning grant applications for the establishment of an infrastructure for eventual Muscular Dystrophy Cooperative Research Centers (MDCRCs). This initiative supports the planning of new or expansion of existing resources for future competitive MDCRCs. These planning grants will enable applicants to effectively organize and integrate multidisciplinary research capacities and core resources to enhance collaborations of basic, clinical, and behavioral science in muscular dystrophy research and to promote cross-disciplinary research training.

Participation in this RFA will not itself be a factor in the review of any Center application. Investigators may respond to current (e.g., RFA AR03-001) or future solicitations for center grant applications without first having participated in this developmental planning initiative.

Investigators interested in applying for support of muscular dystrophy research using mechanisms other than centers or this developmental planning initiative should see NIH PAS01-041, "Therapeutic and Pathogenic Approaches for the Muscular Dystrophies" ([http://www.niams.nih.gov/rtac/funding/grants/pa/pas\\_01\\_041.pdf](http://www.niams.nih.gov/rtac/funding/grants/pa/pas_01_041.pdf)).

## RESEARCH OBJECTIVES

### Background and Rationale

Muscular dystrophies collectively have a high impact on health, affecting tens of thousands of people in the United States alone. The diseases are characterized by progressive weakness and wasting of muscles. Many cases of muscular dystrophy represent new occurrences of disease, where there is no prior family history. Though research has recently revealed much about genetic defects associated with many forms of muscular dystrophy, treatment for the diseases has not changed significantly. There is a need to learn more about pathogenesis of the diseases and improve early detection and screening, diagnosis, treatment, and prevention. Summaries of recent NIH sponsored meetings on this subject may be found at:

[http://www.ninds.nih.gov/news\\_and\\_events/dmdmtngsummary.htm](http://www.ninds.nih.gov/news_and_events/dmdmtngsummary.htm);  
[http://www.niams.nih.gov/ne/reports/sci\\_wrk/2000/fshdexsummary.htm](http://www.niams.nih.gov/ne/reports/sci_wrk/2000/fshdexsummary.htm); and  
[http://www.niams.nih.gov/ne/reports/sci\\_wrk/2002/mdmeet.htm](http://www.niams.nih.gov/ne/reports/sci_wrk/2002/mdmeet.htm).

Given the promising growth of research relevant to muscular dystrophy, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Neurological

Disorders and Stroke (NINDS), and the National Institute of Child Health and Human Development (NICHD) have initiated a program of Muscular Dystrophy Cooperative Research Centers to promote interaction among investigators in the field. Multidisciplinary, multifaceted research is of paramount importance in better understanding the etiology, pathophysiology, and insightful treatment of muscular dystrophy. The program was initiated with the release of RFA AR03-001, which may be found at [http://www.niams.nih.gov/rtac/funding/grants/rfa/ar\\_03\\_001.pdf](http://www.niams.nih.gov/rtac/funding/grants/rfa/ar_03_001.pdf). The MDCRC program represents a quantum increase in the organization and scope of the scientific enterprise related to muscular dystrophy. This RFA, AR03-002, is intended to increase the number and quality of teams and/or sites fully prepared to organize the scientific and infrastructure resources necessary to generate outstanding applications to become Muscular Dystrophy Cooperative Research Centers.

Developmental planning grants are a proven method of facilitating collaborations among teams of researchers who need to interact intensively in order to formulate integrative strategies. Following such focused preparation, research groups are in a far better position to submit well conceptualized and comprehensive center applications.

Therefore, the primary goal of this request is to support early and mid-stage development of interdisciplinary teams of accomplished investigators focused on basic and clinical issues related to muscular dystrophy. This support will provide them with the opportunity to define common goals and objectives, prove the feasibility of their working as a cohesive, interactive research team, and aid in the acquisition of resources, equipment, or administrative support needed to operate an interdisciplinary center. Demonstrating the planning and development interaction of such teams to produce innovative, potentially high-impact approaches to important research problems would position these teams well to apply for support as MDCRCs.

#### Research Objectives

These developmental planning grants will provide institutions with the resources to set in place detailed plans for all of the components that would potentially make them competitive for MDCRC support (see RFA AR03-001, which may be found at [http://www.niams.nih.gov/rtac/funding/grants/rfa/ar\\_03\\_001.pdf](http://www.niams.nih.gov/rtac/funding/grants/rfa/ar_03_001.pdf)). An appropriate Director with expertise in basic or clinical research relevant to muscular dystrophy must be selected as Principal Investigator (PI). In addition, the application must identify a Co-Director with expertise in a complementary field. The PI should have a demonstrated capability to organize, administer and direct the team. It is expected that the Director (PI) and Co-Director will have a substantial

investment in this developmental effort, with the goal of assembling and organizing an outstanding center application. Investigators with the qualifications to be members of the research team, and to contribute to such a unique enterprise, may be located in different geographic locations. Therefore, collaborations among different institutions are encouraged, if scientifically appropriate. The lead investigators should represent major scientific components that will be involved in the relevant proposed Muscular Dystrophy Cooperative Research Center, and each must have demonstrated scientific accomplishment, but they do not need to demonstrate prior interactive research amongst themselves. Plans for center development are encouraged to involve both researchers and potential clinical populations from diverse groups. The Director, using the advice of the lead investigators, will be responsible for the definition of the research goals and objectives of the developmental enterprise, as well as ongoing activities.

#### Characteristics of Responsive Applications

Critical elements of any application submitted in response to this RFA will include (1) an overview of the proposed team, (2) a description of the potential center's central theme and goals, (3) an explanation of how the research team could eventually constitute the backbone of a center, and (4) a plan of development activities. The applicants should describe how the team would achieve its major objectives during the period of support provided under this RFA, and the team's vision of how the center would develop over a period of several years. The discussion would explain the proposed contribution of each team member and the synergism with other team members and research programs.

It is expected that most of the teams that compete for support under this RFA will submit applications for an MDCRC for a future re-issuance of RFA AR03-001, which may be found at [http://www.niams.nih.gov/rtac/funding/grants/rfa/ar\\_03\\_001.pdf](http://www.niams.nih.gov/rtac/funding/grants/rfa/ar_03_001.pdf). However, some teams may be successful in the present competition and decide that their research programs are more suitable for support by R01 or other NIH mechanisms and proceed accordingly. Other teams may decide that they are prepared to apply for full center support without responding to this RFA.

Since the duration and total amount of support provided under the present mechanism are limited, it is not anticipated that totally new or substantial research projects will be entirely funded from this support. However, support for pilot projects of limited scope, or pivotal funding of partially completed projects critical to a future MDCRC application would be appropriate.

#### Activities During Funding Period

It is anticipated that the next request for applications for Muscular Dystrophy Cooperative Research Centers will be issued during summer, 2004, for funding in FY 2005. Since the likely receipt date will be December 2004, applications for the current developmental grants should plan activities and budget funds so that work is completed by that time.

During the course of the developmental planning grant award, the leadership team will be responsible for the design and implementation of planning activities that will lead to a well-developed, conceptually sound application for an MDCRC. The application must include a proposed plan through which scientific synergy can occur on a stable and continuing basis that will incorporate: 1) an organizational structure specifically designed to facilitate intellectual cross-fertilization among team members; 2) a detailed description of core facilities that would support research activities; 3) a plan for the distribution and management of developmental planning grant funds for feasibility testing of new projects; 4) strategies for promoting career development opportunities for new and established investigators and seminars for students and researchers, and a visiting scientists program or other type of training or educational approaches.

The planning activities should emphasize the interface between clinical and basic research and should be structured to meet the needs and level of maturity of the ongoing efforts.

Organizational activities must occur, during which the group will be expected to define:

- The organization and operational structure of the team. This will include planning for leadership by senior investigators, who will be responsible for the overall scientific direction of the program and will also involve delineating mechanisms for involving a dynamic group of investigators at all levels of experience.
- A plan for interactive activities that will occur regularly over the entire course of the developmental planning grant award. Emphasis should be placed on establishing creative, productive interactions designed to promote the cross-fertilization between basic and clinical subdisciplines of research relevant to muscular dystrophy.
- The relationship of the proposed center research to other clinical and epidemiological activities at the host institution(s) where there are possibilities for interaction, for example the ability to participate in clinical trials. There should be discussion of the clinical patient population that can be accessed for studies, including any ongoing muscular dystrophy clinics or surveillance systems.

- A description of the core facilities necessary to support the scientific goals of the program.

Access to equipment and resources is often a problem, especially for multi-disciplinary programs. The establishment of core resources dedicated to team-related projects will provide this access. Initially, core resources may simply be extensions of existing laboratories or facilities, and the definition of a core resource would vary considerably depending on the projects, existing facilities, and the scientific focus of the team.

## MECHANISM OF SUPPORT

This RFA will use NIH Exploratory/Developmental Grant R21 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Future unsolicited, competing-continuation applications based on this project will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures. The anticipated award date is September 2003.

This RFA uses just-in-time concepts. It also uses the modular budgeting format. (See <http://grants.nih.gov/grants/funding/modular/modular.htm>).

## FUNDS AVAILABLE

NIAMS, NINDS, and NICHD intend to commit approximately \$1,000,000 in FY 2003 to fund 4-5 new grants in response to this RFA. Funding for each award will be limited to 6 modules (\$150,000 direct costs) and a project period of one year. An additional module may be requested to accommodate F&A costs for consortium arrangements. Awards are not renewable and supplements are not allowed. Grantees may request a no-cost extension of an R21. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of NIAMS, NINDS, and NICHD provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. There are no plans to reissue this RFA.

Funds provided under this RFA are intended to support activities such as travel for group meetings, partial support for administrative personnel to facilitate the logistics of intensive interaction among investigative teams, support for critical ongoing pilot projects that could demonstrate feasibility in a future MDCRC proposal, development of resource cores, and/or other expenses that are reasonably incurred in activities that are crucial to developing a quality proposal for a center.

## ELIGIBLE INSTITUTIONS

Applications may be submitted by domestic organizations with any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government

## INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

## SPECIAL REQUIREMENTS

Applications for the present RFA will be expected to propose developmental activities in some substantial subset of topics relevant to a possible future muscular dystrophy research center. Only applications that include both basic and clinical research components will be considered responsive to this RFA. The current MDCRC program requires an integrated basic and clinical research program focused on improving knowledge and treatment of muscular dystrophy. Close interaction between basic researchers and clinicians is expected to accelerate the translation of fundamental advances to the clinic.

## WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

- o Direct your questions about scientific/research issues to:

Richard W. Lymn, Ph.D.  
Chief, Muscle Biology Branch

National Institute of Arthritis and Musculoskeletal and Skin Diseases  
One Democracy Plaza  
6701 Democracy Blvd., Suite 800  
Bethesda, MD 20892-4872  
Telephone: (301) 594-5128  
FAX: (301) 480-4543  
Email: [LymnR@mail.nih.gov](mailto:LymnR@mail.nih.gov)

James W. Hanson, M.D.  
Chief, Mental Retardation and Developmental Disabilities Branch  
Center for Research for Mothers and Children  
National Institute of Child Health and Human Development  
6100 Executive Blvd, Room 4B09 MSC 7510  
Bethesda, MD 20892-7510  
Telephone: (301) 496-1383  
FAX: (301) 496-3791  
Email: [hansonj@mail.nih.gov](mailto:hansonj@mail.nih.gov)

Giovanna M. Spinella, M.D.  
Neurogenetics and Development Program  
National Institute of Neurological Disorders and Stroke  
6001 Executive Blvd. Rm. 2132  
Rockville, MD 20892-9527  
Telephone: (301) 496-5745  
FAX: (301) 401-1501  
Email: [gs41b@nih.gov](mailto:gs41b@nih.gov)

o Direct your questions about peer review issues to:

Chief, Review Branch  
Extramural Programs  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
One Democracy Plaza  
6701 Democracy Blvd., Suite 800  
Bethesda, MD 20892-4872  
Telephone: (301) 594-4952  
FAX: (301) 402-2406

Email: [nrb@mail.nih.gov](mailto:nrb@mail.nih.gov)

o Direct your questions about financial or grants management matters to:

Michael G. Morse  
Deputy Grants Management Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
One Democracy Plaza  
6701 Democracy Blvd. Suite 800  
Bethesda, MD 20892-4872  
Telephone: (301) 594-3535  
FAX: (301) 480-5450  
Email: [morsem@mail.nih.gov](mailto:morsem@mail.nih.gov)

Christopher Myers  
Grants Management Officer  
National Institute of Child Health and Human Development  
Building 6100E/Room 8A17  
6100 Executive Blvd. MSC 7510  
Bethesda, MD 20892-7510  
Email: [cm143g@nih.gov](mailto:cm143g@nih.gov)

Sheila Simmons  
Grants Management Specialist  
National Institute of Neurological Disorders and Stroke  
6001 Executive Blvd. Rm. 3250  
Rockville, MD 20892  
Telephone: (301) 496-9231  
FAX: (301) 402-0219  
Email: [simmonss@ninds.nih.gov](mailto:simmonss@ninds.nih.gov)

## LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research

- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Richard W. Lymn, Ph.D.  
Chief, Muscle Biology Branch  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
One Democracy Plaza  
6701 Democracy Blvd., Suite 800  
Bethesda, MD 20892-4872  
Telephone: (301) 594-5128  
FAX: (301) 480-4543  
Email: [LymnR@mail.nih.gov](mailto:LymnR@mail.nih.gov)

#### SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

#### SUPPLEMENTAL INSTRUCTIONS:

##### RESEARCH PLAN

The research plan is limited to 25 pages for R21 applications (exclusive of cited references). Applications that exceed the page limit will be returned without review. Applicants may include up to three relevant appendices to establish background information, but should include no

information unique to the application; the appendices are not to be used to circumvent the page limit of the research plan.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

#### A. FACE PAGE

Complete all items on the face page (Form Page 1) as directed. In the title block, item 1, put "DEVELOPMENTAL PLANNING GRANT FOR MUSCULAR DYSTROPHY RESEARCH CENTER." Mark item 2 "yes" and write in the RFA code AR03-002, as listed in the NIH Guide to Grants and Contracts, and "DEVELOPMENTAL PLANNING GRANTS FOR MUSCULAR DYSTROPHY RESEARCH CENTERS" for the title.

B. BUDGET: Funding under this developmental RFA will be for a maximum of \$150,000 direct costs, which may be budgeted for one year. For those applications that include more than one institution, direct costs of up to \$175,000 may be requested to allow for F&A costs on consortium arrangements.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center For Scientific Review

National Institutes of Health  
6701 Rockledge Drive, Room 1040, MSC 7710  
Bethesda, MD 20892-7710  
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application, including all appendix material, must be sent to:

Chief, Review Branch  
Extramural Programs  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
One Democracy Plaza  
6701 Democracy Blvd., Suite 800  
Bethesda, MD 20892-4872  
[Bethesda, MD 20817 (for express/courier service)]

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

#### PEER REVIEW PROCESS

Applicants should keep in mind that the written application is the basis for the merit review. Site visits are not anticipated. Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIH program staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIH in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the National Advisory Councils for NIAMS, NINDS, and NICHD.

## REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics? What is the likelihood that support of the proposed developmental activities will improve the quality of a subsequent application for a Muscular Dystrophy Cooperative Research Center, and increase the likelihood of success? The review will not emphasize detailed protocols or methods.

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies? Special emphasis will be placed on integration of basic and clinical research components relevant to muscular dystrophy into promising synergistic proposals. The review will not emphasize detailed protocols or methods.

(4) INVESTIGATOR: Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers? The quality of the research team will be given special emphasis in this review. The inclusion of appropriate outstanding investigators, who have not previously been associated with NIH-supported research directly relevant to muscular dystrophy, is encouraged, when the research team as a whole has expertise in muscular dystrophy.

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Are there strong potential resources available at the performance site(s)?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

- o CAREER DEVELOPMENT PLANS: Adequacy of plans for promoting career development opportunities for new and established investigators, such as seminars for students and researchers, a visiting scientists program, or other types of training and educational approaches. What is the likelihood of the success of the proposed strategies?

- o PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

- o INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

- o BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

## RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: January 15, 2003

Application Receipt Date: February 24, 2003

Scientific Review Date: May/June 2003

Advisory Council Date: September 2003

Earliest Date of Award: September 2003

## AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities, including balance among muscular dystrophy research and scientific resource areas

## REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and

Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

#### INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at [http://grants.nih.gov/grants/stem\\_cells.htm](http://grants.nih.gov/grants/stem_cells.htm) and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

**PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:** The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**URLs IN NIH GRANT APPLICATIONS OR APPENDICES:** All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**HEALTHY PEOPLE 2010:** The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

**AUTHORITY AND REGULATIONS:** This program is described in the Catalog of Federal Domestic Assistance Nos. 93.846 (NIAMS), 93.853 (NINDS), and 93.865 (NICHD) and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284)(or other authorizations) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> (cite other relevant policies) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92 (cite other relevant regulations).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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